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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SUPERNUS PHARMACEUTICALS, INC., **Plaintiff,** **v.** **ZYDUS PHARMACEUTICALS (USA) INC. and CADILA HEALTHCARE LIMITED,** **Defendants.**	**Civil Action No. _____** **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiff Supernus Pharmaceuticals, Inc. ("Supernus" or "Plaintiff"), by its undersigned attorneys, for its Complaint against Defendants Zydus Pharmaceuticals (USA) Inc. ("Zydus USA") and Cadila Healthcare Limited ("Zydus Cadila") (collectively, "Zydus" or "Defendants"), alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, involving United States Patent Nos. 8,298,576 ("the

'576 patent"), 8,298,580 ("the '580 patent"), 8,663,683 ("the '683 patent"), 8,877,248 ("the '248 patent"), 8,889,191 ("the '191 patent"), 8,992,989 ("the '989 patent"), 9,549,940 ("the '940 patent"), 9,555,004 ("the '004 patent"), 9,622,983 ("the '983 patent"), and 10,314,790 ("the '790 patent") attached hereto as Exhibits A–J (collectively, "the patents in suit").

THE PARTIES

2. Plaintiff Supernus is a corporation organized and existing under the laws of Delaware, having its principal place of business at 9715 Key West Avenue, Rockville, MD 20850.

3. Upon information and belief, Defendant Zydus USA is a corporation organized and existing under the laws of New Jersey, having its principal place of business at 73 Route 31 North, Pennington, NJ 08534. Upon information and belief, Zydus USA is a wholly-owned subsidiary, directly or indirectly, of Defendant Zydus Cadila. Upon information and belief, Zydus USA acts at the direction of, under the control of, and for the direct benefit of Zydus Cadila and is controlled and/or dominated by Zydus Cadila.

4. Upon information and belief, Defendant Zydus Cadila is a corporation operating and existing under the laws of India, with its principal place of business at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S.G. Highway, Ahmedabad, Gujarat, 382481, India.

5. Upon information and belief, Zydus filed Abbreviated New Drug Application ("ANDA") No. 216167 ("the Zydus ANDA") with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of generic topiramate extended-release capsules containing 200 mg of topiramate ("the Zydus ANDA Product").

6. Upon information and belief, Zydus Cadila and Zydus USA are acting cooperatively with respect to the Zydus ANDA.

7. Upon information and belief, Zydus Cadila and Zydus USA collaborate to develop, manufacture, import, market, and distribute, and/or sell pharmaceutical products, including generic drug products (e.g., Donepezil Hydrochloride Tablets (5 mg and10 mg), Divalproex Sodium Capsules (125 mg), and Gabapentin Tablets (600 mg and 800 mg)), that will be manufactured and sold pursuant to an ANDA throughout the United States, including throughout the State of New Jersey.

8. Upon information and belief, Defendants and/or their affiliates manufacture and/or direct the manufacture of generic pharmaceutical products for which Zydus is the named ANDA applicant. Upon information and belief, Defendants each, directly or indirectly, derive substantial revenue from the sales of such generic pharmaceutical products.

9. Upon information and belief, Zydus will market the Zydus ANDA Product throughout the United States, including in New Jersey, upon approval of the Zydus ANDA.

JURISDICTION AND VENUE

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

11. This Court has personal jurisdiction over Defendants under: (i) Fed. R. Civ. P. 4(k)(1) and N.J. Ct. R. 4:4-4; and/or (ii) Fed. R. Civ. P. 4(k)(2).

12. Upon information and belief, Defendants have purposefully availed themselves of the privilege of doing business in the State of New Jersey by continuously and systematically placing goods in the stream of commerce for distribution and sale throughout the United States, including the State of New Jersey. For example, in Zydus's Annual Report 2020-21, Zydus states that the "Company launched 30 new products in the US generics market" during the year,

filed "22 additional ANDAs [] with the USFDA during the year, taking the cumulative number of ANDA filings to 412," and received "approval for 35 ANDAs during the year," taking the "[c]umulative number of ANDA approvals at the end of the year [to] 317." Zydus Annual Report 2020-21 at 31, https://www.zyduscadila.com/public/pdf/financial/annual/Annual-Report-2020-2021.pdf (accessed September 17, 2021). The Annual Report further states that "[t]he Company is now ranked fifth amongst US generic companies based on prescriptions." Zydus Annual Report 2020-21 at 30, https://www.zyduscadila.com/public/pdf/financial/annual/Annual-Report-2020-2021.pdf (accessed September 17, 2021). Zydus's Annual Report also states that "the Company's formulations business in the US posted a sales of Rs. 65,445 Mio. during the year, up 3%." Zydus Annual Report 2020-21 at 31, https://www.zyduscadila.com/public/pdf/financial/annual/Annual-Report-2020-2021.pdf (accessed September 17, 2021).

13. This Court has personal jurisdiction over Zydus USA at least because, upon information and belief: (i) Zydus USA maintains a principal place of business in New Jersey located at 73 Route 31 North, Pennington, New Jersey 08534; (ii) Zydus USA is doing business in New Jersey and maintains continuous and systematic contacts with this Judicial District; (iii) Zydus USA, together with its parent Zydus Cadila, is in the business of developing and manufacturing generic pharmaceutical products for importation, sale, and/or distribution in the State of New Jersey; (iv) Zydus USA, together with its parent Zydus Cadila, has committed, induced, and/or contributed to acts of patent infringement in New Jersey; and (v) Zydus USA has previously submitted to the jurisdiction of this Court, has availed itself of New Jersey's legal

protections in prior litigations, and previously consented to personal jurisdiction and venue in this Judicial District.[1]

14. According to Defendants' website and Annual Report 2020-21, Zydus USA is based in Pennington, New Jersey, and is a wholly owned subsidiary of Zydus Cadila. Zydus Website, https://zydususa.com/overview/ (accessed September 17, 2021); Zydus Annual Report 2020-21 at 83, https://www.zyduscadila.com/public/pdf/financial/annual/Annual-Report-2020-2021.pdf (accessed September 17, 2021).

15. Upon information and belief, Zydus USA is in the business of, *inter alia*: (i) developing, marketing, distributing, and/or selling generic pharmaceutical products throughout the United States, including throughout the State of New Jersey; (ii) in concert with and/or through its parent(s), including Zydus Cadila, and/or its subsidiaries, the preparation, submission, and filing of ANDAs seeking FDA approval to market generic drugs throughout the United States, including throughout the State of New Jersey; and (iii) alone or in concert with and/or through its parent(s), including Zydus Cadila, and/or its subsidiaries, the distribution of

[1] This Court also has personal jurisdiction over Defendants because Zydus Cadila and Zydus USA have previously submitted to the jurisdiction of this Judicial District and have previously availed themselves of this Judicial District by initiating lawsuits, consenting to this Judicial District's jurisdiction, and asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g.*, *Merck Sharp & Dohme B.V. v. Zydus Pharm. (USA) Inc.*, No. 20-3068 (CCC)(MF) (D.N.J.), ECF No. 23 (showing that Zydus Cadila and Zydus USA did not contest jurisdiction or venue); *Zydus Pharm. (USA) Inc. v. Novartis Pharm. Corp.*, 19-21259 (SRC)(CLW) (D.N.J.), ECF No. 1 (showing that Zydus USA availed itself of the rights, benefits, and privileges of this Court by filing a complaint in the District of New Jersey and admitted to jurisdiction and proper venue); *Takeda Pharm. Co. v. Zydus Pharm. (USA) Inc.*, No. 18-1944 (FLW)(TJB) (D.N.J.), ECF No. 22 (showing that Zydus Cadila and Zydus USA did not oppose jurisdiction or venue, and that Zydus Cadila and Zydus USA filed counterclaims); *Supernus Pharm., Inc. v. Zydus Pharm. (USA) Inc.*, No. 14-7272 (SDW)(SCM) (D.N.J.), ECF No. 29 (showing that Zydus Cadila and Zydus USA did not contest jurisdiction or venue, and that Zydus Cadila and Zydus USA filed counterclaims).

generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey.

16. Upon information and belief, Zydus USA derives substantial revenue from directly or indirectly selling generic pharmaceutical products and/or active pharmaceutical ingredient(s) throughout the United States, including in this Judicial District.

17. Upon information and belief, Zydus USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey with Business Identification Number 0100915422. New Jersey's Division of Revenue and Enterprise Services Website, https://www.njportal.com/DOR/BusinessNameSearch/Search/BusinessName (accessed September 17, 2021). Upon information and belief, Zydus USA is registered with the State of New Jersey's Department of Health as a drug and medical device wholesaler with Registration Number 5003171. New Jersey Department of Health Website, https://healthapps.state.nj.us/fooddrug/fdList.aspx (accessed September 17, 2021). Zydus USA has, therefore, purposefully availed itself of the rights, benefits, and privileges of New Jersey's laws.

18. This Court has personal jurisdiction over Zydus Cadila at least because, upon information and belief: (i) Zydus Cadila has purposefully directed its activities and the activities of Zydus USA at residents and corporate entities within the State of New Jersey; (ii) the claims set forth herein against Zydus Cadila arise out of or relate to those activities; (iii) Zydus Cadila's contacts with the State of New Jersey (direct and indirect) are continuous and systematic; and (iv) it is reasonable and fair for this Court to exercise personal jurisdiction over Zydus Cadila.

19. Upon information and belief, Zydus Cadila derives substantial revenue from directly or indirectly selling generic pharmaceutical products and/or active pharmaceutical ingredient(s) throughout the United States, including in this Judicial District.

20. Upon information and belief, Zydus Cadila is in the business of, *inter alia*: (i) the development and manufacture of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey, and importing generic pharmaceutical products into the United States, including throughout the State of New Jersey; (ii) in concert with and/or through its subsidiaries, including Defendant Zydus USA, the preparation, submission, and filing of ANDAs seeking FDA approval to market generic drugs throughout the United States, including throughout the State of New Jersey; and (iii) in concert with and/or through its subsidiaries, including Defendant Zydus USA, the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey.

21. According to Defendants' website, "Zydus Pharmaceuticals (USA) Inc. is the US generic drug division of a much larger company known as Zydus Cadila Healthcare," which is a "global, fully integrated pharmaceutical company with a presence in 50 countries and is committed to growing its presence around the world and in the United States." Zydus USA Website, https://zydususa.com/ (accessed September 17, 2021). Defendants' website states that "[w]ith the strength and worldwide reputation of Zydus Cadila supporting the US division, Zydus is looking forward to continuing its growth in the US marketplace." Zydus USA Website, https://zydususa.com/overview/ (accessed September 17, 2021). Defendants' website also states that "Zydus has filed over 120 drug master files (DMFs), received final USFDA approval on 283 Abbreviated New Drug Applications (ANDAs), received tentative USFDA approval on 28 ANDAs, and has 133 ANDAs pending approval with the USFDA." Zydus USA Website, https://zydususa.com/overview/ (accessed September 17, 2021). According to Defendants' Annual Report 2020-21, the "US was the second largest contributor to the consolidated revenues of [Zydus Cadila] with 43% share." Zydus Annual Report 2020-21 at 30,

https://www.zyduscadila.com/public/pdf/financial/annual/Annual-Report-2020-2021.pdf (accessed September 17, 2021).

22. Upon information and belief, Zydus's tortious acts of (i) preparing and filing the Zydus ANDA with a paragraph IV certification to the patents in suit for the purpose of obtaining approval to engage in the commercial manufacture, use, offer to sell, and/or sale within the United States, and/or importation into the United States, of the Zydus ANDA Product before the expiration of the patents in suit, and (ii) directing notice of its ANDA submission to Supernus are acts with real and injurious consequences giving rise to this infringement action, including the present and/or anticipated commercial manufacture, use, offer to sell, and/or sale of the Zydus ANDA Product by Defendants before the expiration of the patents in suit throughout the United States, including in this Judicial District. Because defending against an infringement lawsuit such as this one is an inherent and expected part of a generic ANDA filer's business, Zydus should reasonably anticipate being sued in New Jersey.

23. This Court has personal jurisdiction over Zydus at least because, upon information and belief, if the Zydus ANDA is approved, the Zydus ANDA Product will be marketed and distributed by Zydus USA at the direction and control of Zydus Cadila, in the State of New Jersey, prescribed by physicians practicing in the State of New Jersey, dispensed by pharmacies located within the State of New Jersey, and used by patients in the State of New Jersey. Specifically, upon information and belief, if Zydus succeeds in obtaining FDA approval, Zydus will sell the Zydus ANDA Product in the State of New Jersey. Zydus has previously

admitted to marketing and selling drug products in the State of New Jersey and throughout the United States, or to seeking to do the same, directly and through its affiliates.[2]

24. Upon information and belief, Zydus Cadila intends to benefit directly if the Zydus ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of the generic drug products that are the subject of the Zydus ANDA.

25. Upon information and belief, Zydus USA intends to benefit directly if the Zydus ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of the generic drug products that are the subject of the Zydus ANDA.

26. Upon information and belief, Zydus USA acts at the direction, and for the benefit, of Zydus Cadila and is controlled and/or dominated by Zydus Cadila.

27. Upon information and belief, Zydus USA and Zydus Cadila act, operate, and/or hold themselves out to the public as a single, fully integrated business.

28. Venue is proper under 28 U.S.C. §§ 1391(b) and (c) and/or § 1400(b) because, upon information and belief, Zydus USA has a principal place of business in New Jersey and has and will continue to engage in infringing activities in New Jersey.

29. Venue is proper under 28 U.S.C. §§ 1391(b) and (c) and/or § 1400(b) because, upon information and belief, Zydus Cadila is incorporated in India and may be sued in any judicial district in the United States in which the Defendant is subject to the court's personal jurisdiction.

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[2] *See, e.g.*, *Merck Sharp & Dohme B.V. v. Zydus Pharm. (USA) Inc.*, No. 20-3068 (CCC)(MF) (D.N.J.), ECF No. 23 at 3, 5 (showing Zydus admitted to marketing and selling drug products through the United States, including the State of New Jersey, or to seeking to the do the same); *Takeda Pharm. Co. v. Zydus Pharm. (USA) Inc.*, No. 18-1944 (FLW)(TJB) (D.N.J.), ECF No. 22 at 5-6 (showing Zydus admitted to marketing and selling drug products through the United States, including the State of New Jersey, or to seeking to the do the same).

30. Venue is proper under 28 U.S.C. §§ 1391(b) and (c), and/or § 1400(b). Zydus has previously consented to venue in this Judicial District.[3]

FACTS AS TO ALL COUNTS

31. Supernus's Trokendi XR® is sold and marketed under New Drug Application ("NDA") No. 201635, which was approved by FDA for the manufacture and sale of topiramate extended-release capsules, 25 mg, 50 mg, 100 mg, and 200 mg.

32. Trokendi XR® is an antiepileptic drug indicated: (i) as an initial monotherapy for the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 6 years of age and older; (ii) as an adjunctive therapy for the treatment of partial-onset seizures, primary generalized tonic-clonic seizures, and seizures associated with Lennox-Gastaut syndrome in patients 6 years of age and older; and (iii) for the preventive treatment of migraine in patients 12 years of age and older.

33. Trokendi XR®'s recommended dosage: (i) for monotherapy in adults and in pediatric patients 10 years of age and older is 400 mg orally once daily, and in patients 6 to 9 years of age is based on weight; (ii) for adjunctive therapy in adults with partial-onset seizures or Lennox-Gastaut Syndrome is 200 mg to 400 mg orally once daily and with primary generalized tonic-clonic seizures is 400 mg orally once daily, and for adjunctive therapy for patients 6 to 16

[3] *See, e.g.*, *Merck Sharp & Dohme B.V. v. Zydus Pharm. (USA) Inc.*, No. 20-3068 (CCC)(MF) (D.N.J.), ECF No. 23 (showing that Zydus Cadila and Zydus USA did not contest venue); *Zydus Pharm. (USA) Inc. v. Novartis Pharm. Corp.*, 19-21259 (SRC)(CLW) (D.N.J.), ECF No. 1 (showing that Zydus USA availed itself of the rights, benefits, and privileges of this Court by filing a complaint in the District of New Jersey and admitted to proper venue); *Takeda Pharm. Co. v. Zydus Pharm. (USA) Inc.*, No. 18-1944 (FLW)(TJB) (D.N.J.), ECF No. 22 (showing that Zydus Cadila and Zydus USA did not oppose venue); *Supernus Pharm., Inc. v. Zydus Pharm. (USA) Inc.*, No. 14-7272 (SDW)(SCM) (D.N.J.), ECF No. 29 (showing that Zydus Cadila and Zydus USA did not contest venue).

years of age with partial-onset seizures, primary generalized tonic-clonic seizures, or seizures associated with Lennox-Gastaut syndrome is approximately 5 mg/kg to 9 mg/kg orally once daily; and (iii) for the preventive treatment of migraine in patients 12 years of age and older is 100 mg once daily.

34. FDA's publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "*Orange Book*") lists ten (10) patents, specifically the '576, '580, '683, '248, '191, '989, '940, '004, '983, and '790 patents, as covering Supernus's Trokendi XR®. Pursuant to 21 U.S.C. §§ 355(b)(1) and 355(c)(2), these ten (10) patents were submitted to FDA with or after the approval of NDA No. 201635.

35. The '576 patent, titled "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on October 30, 2012, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '576 patent.

36. The '580 patent, titled "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on October 30, 2012, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '580 patent.

37. The '683 patent, titled "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on March 4, 2014, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '683 patent.

38. The '248 patent, titled "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on November 4, 2014, to

Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '248 patent.

39. The '191 patent, titled "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on November 18, 2014, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '191 patent.

40. The '989 patent, titled "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on March 31, 2015, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '989 patent.

41. The '940 patent, titled "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on January 24, 2017, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '940 patent.

42. The '004 patent, titled "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on January 31, 2017, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '004 patent.

43. The '983 patent, titled "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on April 18, 2017, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '983 patent.

44. The '790 patent, titled "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on June 11, 2019, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '790 patent.

45. In 2014, Zydus submitted ANDA No. 207382 seeking approval from the FDA to engage in the commercial use, manufacture, sale, offer for sale, or importation of generic 25 mg, 50 mg, and 100 mg topiramate extended-release capsules ("Zydus Products")—a generic version of Trokendi XR®. *See Supernus Pharm., Inc. v. Zydus Pharm. (USA) Inc.*, No. 14-7272 (SDW)(SCM) (D.N.J.) ("Prior Lawsuit"), ECF No. 1. Supernus sued Zydus in the District of New Jersey asserting that the Zydus Products, if sold and marketed, would infringe certain patents. *See* Prior Lawsuit, ECF No. 1. The Prior Lawsuit against Zydus was settled, and the parties entered into settlement and license agreements (referred herein separately as "Settlement Agreement" and "License Agreement") that permitted Zydus to launch the Zydus Products on January 1, 2023, or earlier under certain circumstances. *See* https://ir.supernus.com/news-releases/news-release-details/supernus-announces-settlement-zydus-trokendi-xrr-patent (accessed September 17, 2021); https://www.sec.gov/Archives/edgar/data/1356576/000110465917031191/a17-10293_1ex10d1.htm (accessed September 17, 2021) (attached hereto as Exhibit K).

46. On or about August 5, 2021, Zydus sent a letter purportedly pursuant to 21 U.S.C. § 355(j)(2)(B) and Section 505(j)(2)(B) of the Food, Drug, and Cosmetic Act ("FDCA") regarding the Zydus ANDA Product and the '576, '580, '683, '248, '191, '989, '940, '004, '983, and '790 patents (the "August 5 Notice Letter") to Supernus at 9715 Key West Ave., Rockville, MD 20850.

47. The August 5 Notice Letter was signed by Brij Khera, Ph.D., Executive Vice President and Chief Legal Officer of Zydus USA.

48. Upon information and belief, the Zydus ANDA identifies Trokendi XR® (topiramate extended-release capsules), 200 mg as the reference listed drug.

49. Upon information and belief, the Zydus ANDA Product is topiramate extended-release capsules, 200 mg.

50. Upon information and belief, the proposed prescribing information for the Zydus ANDA Product includes a header titled "Indications and Usage" and states that the Zydus ANDA Product is indicated: (i) as an initial monotherapy for the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 6 years of age and older; (ii) as an adjunctive therapy for the treatment of partial-onset seizures, primary generalized tonic-clonic seizures, and seizures associated with Lennox-Gastaut syndrome in patients 6 years of age and older; and (iii) for the preventive treatment of migraine in patients 12 years of age and older.

51. Upon information and belief, the proposed prescribing information for the Zydus ANDA Product includes a header titled "Dosage and Administration" and states that: (i) the recommended dose for monotherapy in adults and in pediatric patients 10 years of age and older is 400 mg orally once daily, and dosing in patients 6 to 9 years of age is based on weight; (ii) the recommended total daily dose as adjunctive therapy in adults with partial-onset seizures or Lennox-Gastaut Syndrome is 200 mg to 400 mg orally once daily and with primary generalized tonic-clonic seizures is 400 mg orally once daily, and the recommended total daily dose as adjunctive therapy for patients 6 to 16 years of age with partial-onset seizures, primary generalized tonic-clonic seizures, or seizures associated with Lennox-Gastaut syndrome is approximately 5 mg/kg to 9 mg/kg orally once daily; and (iii) the recommended total daily dose

as treatment for the preventive treatment of migraine in patients 12 years of age and older is 100 mg once daily.

52. Upon information and belief, the proposed prescribing information for the Zydus ANDA Product will also state under the header "Dosage and Administration" that the Zydus ANDA Product can be taken without regard to meals, should be swallowed whole and intact, and should not be sprinkled on food, chewed, or crushed.

53. Upon information and belief, Zydus Cadila and Zydus USA acted in concert to develop the Zydus ANDA Product and/or seek approval from the FDA to sell the Zydus ANDA Product throughout the United States, including within this Judicial District.

54. Upon information and belief, both Zydus Cadila and Zydus USA participated in the preparation and/or filing of the Zydus ANDA.

55. Upon information and belief, Zydus manufactured the Zydus ANDA Product for development and use in preparing and filing the Zydus ANDA.

56. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(7) requires that such a letter include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement must include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)-(ii).

57. Upon information and belief, as of the date of the August 5 Notice Letter, Zydus was aware of the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

58. Contrary to Defendants' contentions in the August 5 Notice Letter, the License Agreement does not authorize or under any circumstances grant Zydus permission to manufacture, have manufactured, import, use, or market in, into, or for the United States the Zydus ANDA Product. *See* Exhibit K.

59. The August 5 Notice Letter alleges that all of the patents in suit are invalid. The Settlement Agreement and License Agreement specifically prohibit Defendants from challenging the validity or enforceability of most of the patents in suit. *See* Exhibit K.

60. Supernus and Zydus did not reach agreement on mutually acceptable terms for an Offer of Confidential Access pursuant to 21 U.S.C. § 355(j)(5)(C) and 21 C.F.R. § 314.95(c)(8). As of the filing of this Complaint, Zydus has not produced the Zydus ANDA to Supernus.

FIRST COUNT
(Defendants' Infringement of the '576 Patent)

61. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

62. Upon information and belief, Zydus's submission and filing of the Zydus ANDA with a paragraph IV certification to the '576 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the Zydus ANDA Product before the expiration of the '576 patent is an act of infringement of the '576 patent by Zydus of one or more claims of the '576 patent under 35 U.S.C. § 271(e)(2)(A).

63. Upon information and belief, Zydus will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Zydus ANDA Product upon, or in anticipation of, FDA approval of the Zydus ANDA.

64. Upon information and belief, Zydus's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Zydus ANDA Product will infringe, directly and/or indirectly, one or more claims of the '576 patent under 35 U.S.C. § 271.

65. Upon information and belief, the commercial offering for sale and/or sale of the Zydus ANDA Product by Zydus will induce and/or contribute to third-party infringement of one or more claims of the '576 patent under 35 U.S.C. § 271.

66. Upon information and belief, the factual and legal bases in the August 5 Notice Letter regarding the '576 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

67. Zydus acted without a reasonable basis for believing that it would not be liable for infringement of the '576 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

68. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Zydus is preliminarily and permanently enjoined by this Court.

SECOND COUNT
(Defendants' Infringement of the '580 Patent)

69. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

70. Upon information and belief, Zydus's submission and filing of the Zydus ANDA with a paragraph IV certification to the '580 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the Zydus ANDA Product before the expiration of the '580 patent is an act of infringement of the '580 patent by Zydus of one or more claims of the '580 patent under 35 U.S.C. § 271(e)(2)(A).

71. Upon information and belief, Zydus will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Zydus ANDA Product upon, or in anticipation of, FDA approval of the Zydus ANDA.

72. Upon information and belief, Zydus's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Zydus ANDA Product will infringe, directly and/or indirectly, one or more claims of the '580 patent under 35 U.S.C. § 271.

73. Upon information and belief, the commercial offering for sale and/or sale of the Zydus ANDA Product by Zydus will induce and/or contribute to third-party infringement of one or more claims of the '580 patent under 35 U.S.C. § 271.

74. Upon information and belief, the factual and legal bases in the August 5 Notice Letter regarding the '580 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

75. Zydus acted without a reasonable basis for believing that it would not be liable for infringement of the '580 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

76. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Zydus is preliminarily and permanently enjoined by this Court.

THIRD COUNT
(Defendants' Infringement of the '683 Patent)

77. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

78. Upon information and belief, Zydus's submission and filing of the Zydus ANDA with a paragraph IV certification to the '683 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the Zydus ANDA Product before the expiration of the '683 patent is an act of infringement of the '683 patent by Zydus of one or more claims of the '683 patent under 35 U.S.C. § 271(e)(2)(A).

79. Upon information and belief, Zydus will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Zydus ANDA Product upon, or in anticipation of, FDA approval of the Zydus ANDA.

80. Upon information and belief, Zydus's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Zydus ANDA Product will infringe, directly and/or indirectly, one or more claims of the '683 patent under 35 U.S.C. § 271.

81. Upon information and belief, the commercial offering for sale and/or sale of the Zydus ANDA Product by Zydus will induce and/or contribute to third-party infringement of one or more claims of the '683 patent under 35 U.S.C. § 271.

82. Upon information and belief, the factual and legal bases in the August 5 Notice Letter regarding the '683 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

83. Zydus acted without a reasonable basis for believing that it would not be liable for infringement of the '683 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

84. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Zydus is preliminarily and permanently enjoined by this Court.

FOURTH COUNT
(Defendants' Infringement of the '248 Patent)

85. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

86. Upon information and belief, Zydus's submission and filing of the Zydus ANDA with a paragraph IV certification to the '248 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the Zydus ANDA Product before the expiration of the '248 patent is an act of infringement of the '248 patent by Zydus of one or more claims of the '248 patent under 35 U.S.C. § 271(e)(2)(A).

87. Upon information and belief, Zydus will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Zydus ANDA Product upon, or in anticipation of, FDA approval of ANDA No. 216167.

88. Upon information and belief, Zydus's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Zydus ANDA Product will infringe, directly and/or indirectly, one or more claims of the '248 patent under 35 U.S.C. § 271.

89. Upon information and belief, the commercial offering for sale and/or sale of the Zydus ANDA Product by Zydus will induce and/or contribute to third-party infringement of one or more claims of the '248 patent under 35 U.S.C. § 271.

90. Upon information and belief, the factual and legal bases in the August 5 Notice Letter regarding the '248 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

91. Zydus acted without a reasonable basis for believing that it would not be liable for infringement of the '248 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

92. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Zydus is preliminarily and permanently enjoined by this Court.

FIFTH COUNT
(Defendants' Infringement of the '191 Patent)

93. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

94. Upon information and belief, Zydus's submission and filing of the Zydus ANDA with a paragraph IV certification to the '191 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United

States of the Zydus ANDA Product before the expiration of the '191 patent is an act of infringement of the '191 patent by Zydus of one or more claims of the '191 patent under 35 U.S.C. § 271(e)(2)(A).

95. Upon information and belief, Zydus will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Zydus ANDA Product upon, or in anticipation of, FDA approval of the Zydus ANDA.

96. Upon information and belief, Zydus's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Zydus ANDA Product will infringe, directly and/or indirectly, one or more claims of the '191 patent under 35 U.S.C. § 271.

97. Upon information and belief, the commercial offering for sale and/or sale of the Zydus ANDA Product by Zydus will induce and/or contribute to third-party infringement of one or more claims of the '191 patent under 35 U.S.C. § 271.

98. Upon information and belief, the factual and legal bases in the August 5 Notice Letter regarding the '191 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

99. Zydus acted without a reasonable basis for believing that it would not be liable for infringement of the '191 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

100. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Zydus is preliminarily and permanently enjoined by this Court.

SIXTH COUNT
(Defendants' Infringement of the '989 Patent)

101. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

102. Upon information and belief, Zydus's submission and filing of the Zydus ANDA with a paragraph IV certification to the '989 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the Zydus ANDA Product before the expiration of the '989 patent is an act of infringement of the '989 patent by Zydus of one or more claims of the '989 patent under 35 U.S.C. § 271(e)(2)(A).

103. Upon information and belief, Zydus will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Zydus ANDA Product upon, or in anticipation of, FDA approval of the Zydus ANDA.

104. Upon information and belief, Zydus's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Zydus ANDA Product will infringe, directly and/or indirectly, one or more claims of the '989 patent under 35 U.S.C. § 271.

105. Upon information and belief, the commercial offering for sale and/or sale of the Zydus ANDA Product by Zydus will induce and/or contribute to third-party infringement of one or more claims of the '989 patent under 35 U.S.C. § 271.

106. Upon information and belief, the factual and legal bases in the August 5 Notice Letter regarding the '989 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

107. Zydus acted without a reasonable basis for believing that it would not be liable for infringement of the ’989 patent, thus rendering this case “exceptional” under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys’ fees under 35 U.S.C. § 285.

108. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Zydus is preliminarily and permanently enjoined by this Court.

SEVENTH COUNT
(Defendants’ Infringement of the ’940 Patent)

109. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

110. Upon information and belief, Zydus’s submission and filing of the Zydus ANDA with a paragraph IV certification to the ’940 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the Zydus ANDA Product before the expiration of the ’940 patent is an act of infringement of the ’940 patent by Zydus of one or more claims of the ’940 patent under 35 U.S.C. § 271(e)(2)(A).

111. Upon information and belief, Zydus will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Zydus ANDA Product upon, or in anticipation of, FDA approval of the Zydus ANDA.

112. Upon information and belief, Zydus’s commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Zydus ANDA Product will infringe, directly and/or indirectly, one or more claims of the ’940 patent under 35 U.S.C. § 271.

113. Upon information and belief, the commercial offering for sale and/or sale of the Zydus ANDA Product by Zydus will induce and/or contribute to third-party infringement of one or more claims of the '940 patent under 35 U.S.C. § 271.

114. Upon information and belief, the factual and legal bases in the August 5 Notice Letter regarding the '940 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

115. Zydus acted without a reasonable basis for believing that it would not be liable for infringement of the '940 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

116. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Zydus is preliminarily and permanently enjoined by this Court.

EIGHTH COUNT
(Defendants' Infringement of the '004 Patent)

117. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

118. Upon information and belief, Zydus's submission and filing of the Zydus ANDA with a paragraph IV certification to the '004 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the Zydus ANDA Product before the expiration of the '004 patent is an act of infringement of the '004 patent by Zydus of one or more claims of the '004 patent under 35 U.S.C. § 271(e)(2)(A).

119. Upon information and belief, Zydus will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Zydus ANDA Product upon, or in anticipation of, FDA approval of the Zydus ANDA.

120. Upon information and belief, Zydus's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Zydus ANDA Product will infringe, directly and/or indirectly, one or more claims of the '004 patent under 35 U.S.C. § 271.

121. Upon information and belief, the commercial offering for sale and/or sale of the Zydus ANDA Product by Zydus will induce and/or contribute to third-party infringement of one or more claims of the '004 patent under 35 U.S.C. § 271.

122. Upon information and belief, the factual and legal bases in the August 5 Notice Letter regarding the '004 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

123. Zydus acted without a reasonable basis for believing that it would not be liable for infringement of the '004 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

124. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Zydus is preliminarily and permanently enjoined by this Court.

NINTH COUNT
(Defendants' Infringement of the '983 Patent)

125. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

126. Upon information and belief, Zydus's submission and filing of the Zydus ANDA with a paragraph IV certification to the '983 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the Zydus ANDA Product before the expiration of the '983 patent is an act of infringement of the '983 patent by Zydus of one or more claims of the '983 patent under 35 U.S.C. § 271(e)(2)(A).

127. Upon information and belief, Zydus will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Zydus ANDA Product upon, or in anticipation of, FDA approval of the Zydus ANDA.

128. Upon information and belief, Zydus's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Zydus ANDA Product will infringe, directly and/or indirectly, one or more claims of the '983 patent under 35 U.S.C. § 271.

129. Upon information and belief, the commercial offering for sale and/or sale of the Zydus ANDA Product by Zydus will induce and/or contribute to third-party infringement of one or more claims of the '983 patent under 35 U.S.C. § 271.

130. Upon information and belief, the factual and legal bases in the August 5 Notice Letter regarding the '983 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

131. Zydus acted without a reasonable basis for believing that it would not be liable for infringement of the '983 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

132. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Zydus is preliminarily and permanently enjoined by this Court.

TENTH COUNT
(Defendants' Infringement of the '790 Patent)

133. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

134. Upon information and belief, Zydus's submission and filing of the Zydus ANDA with a paragraph IV certification to the '790 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the Zydus ANDA Product before the expiration of the '790 patent is an act of infringement of the '790 patent by Zydus of one or more claims of the '790 patent under 35 U.S.C. § 271(e)(2)(A).

135. Upon information and belief, Zydus will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Zydus ANDA Product upon, or in anticipation of, FDA approval of the Zydus ANDA.

136. Upon information and belief, Zydus's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Zydus ANDA Product will infringe, directly and/or indirectly, one or more claims of the '790 patent under 35 U.S.C. § 271.

137. Upon information and belief, the commercial offering for sale and/or sale of the Zydus ANDA Product by Zydus will induce and/or contribute to third-party infringement of one or more claims of the '790 patent under 35 U.S.C. § 271.

138. Upon information and belief, the factual and legal bases in the August 5 Notice Letter regarding the '790 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

139. Zydus acted without a reasonable basis for believing that it would not be liable for infringement of the '790 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

140. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Zydus is preliminarily and permanently enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Supernus respectfully requests the following relief:

i. A Judgment declaring that the patents in suit are valid and enforceable;

ii. A Judgment, pursuant to 35 U.S.C. § 271(e)(2)(A), declaring that the submission to FDA and filing of ANDA No. 216167 with a paragraph IV certification for the purpose of obtaining approval for the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the Zydus ANDA Product was an act of infringement of the patents in suit by Defendants;

iii. A Judgment pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), declaring that the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of the Zydus ANDA Product before the expiration of the patents in suit (including any regulatory extensions) would directly and/or indirectly infringe the patents in suit;

iv. An Order, pursuant to 35 U.S.C. §§ 271(e)(4)(A), 281, and 283, that the effective date of any approval of the Zydus ANDA Product shall be no earlier than the date on which the patents in suit expire (including any regulatory extensions);

v. An Order, pursuant to 35 U.S.C. §§ 271(e)(4)(B), 281, and 283, preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees, and attorneys, and any person in active concert or participation or privity with Defendants, from engaging in the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation in the United States of the Zydus ANDA Product until the expiration of the patents in suit (including any regulatory extensions);

vi. A Judgment, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, awarding Supernus damages or other monetary relief if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States any product that is the subject of ANDA No. 216167 that infringes the patents in suit;

vii. A Judgment, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, declaring that Defendants' infringement of the patents in suit is willful and awarding Supernus enhanced damages if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States any product that is the subject of ANDA No. 216167 that infringes the patents in suit (including any regulatory extensions);

viii. A Judgment, pursuant to 35 U.S.C. § 285, declaring that this is an exceptional case and awarding Supernus its attorneys' fees and costs; and

ix. Such other and further relief as this Court may deem just and proper.

Dated: September 17, 2021

By: s/ William C. Baton

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1

I hereby certify that the matter in controversy involves the same plaintiff, same drug product, and same patents that are at issue in the matters captioned *Supernus Pharmaceuticals, Inc. v. Ajanta Pharma Ltd.*, C.A. No. 21-6964 (FLW)(LHG) (D.N.J.), *Supernus Pharmaceuticals, Inc. v. Torrent Pharmaceuticals Ltd.*, C.A. No. 21-14268 (FLW)(LHG) (D.N.J.), *Supernus Pharmaceuticals, Inc. v. Lupin Limited*, C.A. No. 21-1293 (NM) (D. Del.), and *Supernus Pharmaceuticals, Inc. v. Zydus Pharmaceuticals (USA) Inc.*, C.A. No. (not yet assigned) (S.D.N.Y.).

To the best of my knowledge, this matter is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Dated: September 17, 2021

By: s/ William C. Baton

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